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| 10/058,797 | 01/30/2002 | Paul Lum | 10001024 | 4719 |

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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
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EXAMINER

SIEFKE, SAMUEL P

ART UNIT PAPER NUMBER

1743

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,797

Applicant(s)

LUM ET AL.

Examiner

Samuel P. Siefke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 3-11 and 20-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-6, 20 and 22-24 is/are allowed.
- 6) ☒ Claim(s) 3, 7-11, 21 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 7-11, 21, 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear and indefinite how a collapsor comprising at least one bearing chosen from roller bearings and ball bearings has any relationship with the plungers of claim 7 and the blade of claim 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **7, 21** and **25-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chianese (USPN 5,804,141) in view of Salisbury (USPN 2,625,932).

Chianese discloses a reagent strip slide treating apparatus that comprises a reagent strip slide treating apparatus includes a reagent strip comprised of a plurality of chambers. A reagent passageway on the strip connects to each of the chambers and connects to a common passageway. The chambers are arranged at variable predetermined distances along the strip. A double slide is provided which is comprised of a first and a second slide spaced apart by a predetermined distance and adapted to have therebetween biological material to be treated sequentially by a plurality of reagents. A tube connects the common passageway of the reagent strip to the space between the space slides. The capsules containing reagents are provided within the chambers on the strip. The capsules are provided with thin walls which are adapted to burst upon the application of pressure. A press moving at a constant speed is provided to press the reagent strip and capsules in the chambers causing the capsules to burst. The spacing between the chambers determines the timing of the application of the reagents. The strip may preferably be straight, although it may be curved such as an arc or a roller may be mounted on a radial arm (abstract, fig. 1-7). Regarding the limitation of the cartridge comprises a rigid core adjacent to said pliable surface and opposite the collapsor, this would be the reagent strip 10, it is rigid and aids in providing an opposite stationary force when the collapsor (roller) is rolled over the chamber.

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Chianese discloses chambers 20 E and F illustrate a protocol step where two reagents are to be applied simultaneously. This commonly occurs where the two reagents cannot be premixed in advance, but have to be mixed at the time of application (col. 5, lines 8-11). Chianese states that any suitable means of sequentially applying pressure to reagent strip 10 at a constant rate of speed to compress or squeeze the chambers 20 with the capsules 22 may be utilized in carrying out the present invention.

Chianese does not teach a collapsor being a series of plungers.

Salisbury micro pump for pumping biological fluids that comprises a flexible tube 107 that sits in rigid casing 106 (Figures 5-10). Valve plungers 118 and 118(1) are arranged one at either end of the piston 115, and are operated by the cams 112 in alternating sequences. The valve plungers and connecting rods are guided for vertical reciprocating movement. Rotation of shaft 111 through cams 112 and 113, depress the valve plungers 118 and 118(1) and piston 115. In Fig. 9 rotating in a clockwise direction, plunger 118 will depress first and close off tube 107 at the left end of the piston 115 as viewed in fig. 8. Then piston 115 gradually collapses the portion of the tube between valve plungers 118 and 118(1) and forces the contents of the tube portion along the tube in the direction indicated by arrow 119 (col. 7, lines 3-52). This sequential sample movement in a flexible tube is well known in the art. Therefore, it would have been obvious to one having an ordinary skill in the art to modify Chianese to provide the pump of Salisbury because it is known in the art that metering pumps that employ pistons and plungers impart sequential forces on structures for movement of

fluid through flexible tubes. Such an application of a plunger would provide a gradual movement of fluid instead of rapid, allowing for diffusive mixing.

Claims 3 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chianese (USPN 5,804,141) in view of Woodbridge, III (USPN 4,065,263).

Chianese discloses a reagent strip slide treating apparatus that comprises a reagent strip slide treating apparatus includes a reagent strip comprised of a plurality of chambers. A reagent passageway on the strip connects to each of the chambers and connects to a common passageway. The chambers are arranged at variable predetermined distances along the strip. A double slide is provided which is comprised of a first and a second slide spaced apart by a predetermined distance and adapted to have therebetween biological material to be treated sequentially by a plurality of reagents. A tube connects the common passageway of the reagent strip to the space between the space slides. The capsules containing reagents are provided within the chambers on the strip. The capsules are provided with thin walls which are adapted to burst upon the application of pressure. A press moving at a constant speed is provided to press the reagent strip and capsules in the chambers causing the capsules to burst. The spacing between the chambers determines the timing of the application of the reagents. The strip may preferably be straight, although it may be curved such as an arc or a roller may be mounted on a radial arm (abstract, fig. 1-7). Regarding the limitation of the cartridge comprises a rigid core adjacent to said pliable surface and opposite the collapsor, this would be the reagent strip 10, it is rigid and aids in providing an opposite stationary force when the collapsor (roller) is rolled over the chamber.

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Chianese discloses chambers 20 E and F illustrate a protocol step where two reagents are to be applied simultaneously. This commonly occurs where the two reagents cannot be premixed in advance, but have to be mixed at the time of application (col. 5, lines 8-11). Chianese states that any suitable means of sequentially applying pressure to reagent strip 10 at a constant rate of speed to compress or squeeze the chambers 20 with the capsules 22 may be utilized in carrying out the present invention.

Chianese does not teach a collapsor being a series of plungers.

Woodbridge teaches a thin, flat, hollow test strip the interior of which is filled with an inert liquid medium and which includes at least one physical, chemical, biological or detecting station wherein a blister of sample may be introduced into the top of said strip and positively propelled forwardly ahead of a pinch line through the inert liquid medium to each station. Woodbridge teaches several types of blister propelling means that comprises a doctor blade or knife technique as illustrated in FIG. 7. Taking a look at fig. 7. the blade has a longitudinal axis oriented at an acute angle less than perpendicular to the surface 38 so that the blade urges the fluid across the cartridge.

Woodbridge states that the doctor blade 42 can be used interchangeably in place of the set of rollers 32 shown in figures 1-3 (col. 8, lines 29-36). There fore it would have been obvious to one having an ordinary skill in the art to modify Chianese to employ the blade of Woodbridge to displace the biological fluid in the cartridge because it is known that the blade and rollers are interchangeable and perform the same function.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chianese (USPN 5,804,141) in view of Woodbridge, III (USPN 4,065,263) and in further view of Weigl et al. (SUPN 6,409,832).

Chianese discloses a reagent strip slide treating apparatus that comprises a reagent strip slide treating apparatus includes a reagent strip comprised of a plurality of chambers.

The modified Chianese does not teach a system of checkvalves.

Weigl teaches a microfluidic structure that comprises a system of checkvalves for allowing fluid flow in one direction only such that back flow is prevented (col. 13, lines 1-5). It would have been obvious to one having an ordinary skill in the art to modify Chianese to include the checkvalves of Weigl for only allowing fluid flow in one direction such that back flow is prevented.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chianese (USPN 5,804,141) in view of Woodbridge, III (USPN 4,065,263) in view of Weigl et al. (USPN 6,409,832) and in further view of Dapprich (USPN 6,585,939).

Chianese discloses a reagent strip slide treating apparatus that comprises a reagent strip slide treating apparatus includes a reagent strip comprised of a plurality of chambers.

The modified Chianese does not teach a self-sealing membrane.

Dapprich teaches a microstructure for use in biological assays and reactions. The microstructure is fabricated from a cast or molded polymer material such as polydimethylsiloxane (PDMS). PDMS is a self-sealing material and the walls between

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the self-sealing cells 12 in the microstructure function to isolated each sample and/or reagent and prevent cross contamination (col. 8, lines 59-67). It would have been obvious to one having an ordinary skill in the art to modify Chianese to include the self-sealing membrane of Dapprich in order to prevent cross contamination between reagents and also for ease of manufacturing the microfluidic structure.

Claim **30** is rejected under 35 U.S.C. 103(a) as being unpatentable over Chianese (USPN 5,804,141) in view of Woodbridge, III (USPN 4,065,263) and in further view of Dapprich (USPN 6,585,939).

Chianese discloses a reagent strip slide treating apparatus that comprises a reagent strip slide treating apparatus includes a reagent strip comprised of a plurality of chambers.

The modified Chianese does not teach a self-sealing membrane.

Dapprich teaches a microstructure for use in biological assays and reactions. The microstructure is fabricated from a cast or molded polymer material such as polydimethylsiloxane (PDMS). PDMS is a self-sealing material and the walls between the self-sealing cells 12 in the microstructure function to isolated each sample and/or reagent and prevent cross contamination (col. 8, lines 59-67). It would have been obvious to one having an ordinary skill in the art to modify Chianese to include the self-sealing membrane of Dapprich in order to prevent cross contamination between reagents and also for ease of manufacturing the microfluidic structure.

Allowable Subject Matter

Claims **4-6, 20** and **22-24** are allowed.

The following is an examiner's statement of reasons for allowance: Claim 5 is allowable because the prior art does not teach a micro pump having a collapsor surface with protrusions having predetermined spacing, the predetermined spacing creating corresponding concavities in the pliable surface as the collapsor collapses the pliable surface against the rigid core, and displacement of the corresponding cavities causing a predetermined amount of biological fluid to be delivered from the cartridge.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

Applicant's arguments with respect to claims 3-4,7-11,21,25-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

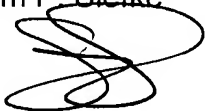
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



September 13, 2005



Jill Warden
Supervisory Patent Examiner
Technology Center 1700